Claims 56-66 have been added herein.

Claims 1-15 and 56-66 are now pending in the application.

2.3 REMARKS REGARDING THE NOTICE OF NON-COMPLIANT AMENDMENT

Applicants note that the stated reason for the Notice of Non-Compliant Amendment mailed November 9, 2005 was seeking to clarify the "status" of claims in the Response to the Restriction Requirement mailed August 25, 2005 to the Office. In particular, the Examiner stated that it was unclear whether claims 16-55 were "canceled" or "withdrawn" from consideration because of the prefatory remark made on page two of the originally-submitted response that indicated certain claims were no longer under consideration in view of the prior restriction requirement.

Applicants note for the record that the claims in question *were* properly identified with the claim status identifiers as required under the modified rules, and that the correct status of the claims is provided herein.

In the future, should the Examiner have any questions regarding a response filed by Applicants, she is welcomed to contact the undersigned representative for clarification by telephone. Mindful of patent term considerations, and the protracted nature of examination currently in TC1600 , the Applicants would appreciate such efforts by the Office so that the examination of the present case is not unnecessarily lengthened by the minutiae of the technicalities of the claim "identifiers".

In the interest of providing a full, complete, and timely response to the outstanding Notice, Applicants herein file a complete answer to the Non-Compliant Amendment Notice and ask that the case be examined with all due speed.

2.4 THE RESTRICTION

The Action subjected the present application to the following fifteen-way restriction:

Group 1 – Claims 1-15 drawn to methods of nuclear transfer.

Group 2 – Claims 16-33 drawn to methods of producing cloned animal embryos by transferring a segregated donor nucleus in the G1 stage of the cell cycle into an enucleated recipient cell.

Group 3 – Claims 34-46 drawn to methods of producing an embryonic cell line.

Group 4 – Claims 49-51 drawn to methods of therapeutic cloning and methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue, wherein the disease is a neurological disorder.

Group 5 – Claims 49-51 drawn to methods of therapeutic cloning and methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue, wherein the disease is diabetes.

Group 6 – Claim 49-51 drawn to methods of therapeutic cloning and methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue, wherein the disease is heart disease.

Group 7 – Claim 49-51 drawn to methods of therapeutic cloning and methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue wherein the disease is muscular dystrophy.

Group 8 – Claims 49-51, drawn to methods of therapeutic cloning and methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue, wherein the disease is various hereditary diseases.

Group 9 – Claims 49-51, drawn to methods of therapeutic cloning and methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue, wherein the disease is a specific cancer.

Group 10 – Claims 49-51 drawn to methods of therapeutic cloning and methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue wherein the disease is spinal cord injury.

Group 11 – Claims 49-51 drawn to methods of therapeutic cloning and methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue, wherein the disease is burns.

Group 12 – Claims 49-51 drawn to methods of therapeutic cloning and methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue wherein the disease is other afflictions.

Group 13 – Claim 53 drawn to a method of drug discovery or toxicology testing of drugs in vitro.

Group 14 – Claim 54 drawn to a method of xenotransplantation.

Group 15 – Claims 55-56 drawn to methods of gene therapy.

(Applicants note for the record that no claim 56 was pending, so the alleged "Group 15" invention should have been drawn only to a single claim, claim 55).

2.5 THE ALLEGED RESTRICTION IS IMPROPER

Page 3 of the action states "The inventions listed as Groups I-VII (*sic*) do not relate to a single general inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same or corresponding special technical features....."

Applicants respectfully traverse, and are mystified as to this statement by the Office, particularly in view of the fact that during the PCT phase of prosecution ***NO LACK OF UNITY OF INVENTION*** was found. In fact, examination of novelty, inventive step, and industrial applicability was conducted on *ALL* pending claims, and original claims 1-56 of the PCT case were *all* found to be allowable in view of the prior art of record. The International Preliminary Examination Report did NOT hold that there was a lack of a unifying special technical feature, nor did they find a lack of unity.

As such, Applicants believe that the Restriction Requirement is improper in its entirety, and respectfully requests that it be withdrawn.

2.6 THE ALLEGED RESTRICTION IS INCOMPLETE

According to M. P. E. P. § 814, "the separate inventions should be identified by a grouping of the claims with a short description of the total extent of the invention claimed in each group, specifying the type or relationship of each group as by stating the group is drawn to a process, or to a sub-combination, or to a product, etc., and should indicate the classification or separate status of each group, as for example, by class and subclass." (Emphasis added)

Applicants note for the record that the holding in the present Restriction Requirement ***does not*** identify the classification of the allegedly distinct inventions by class and subclass, as required by the statutes, and as such, is incomplete as defined by Office practice guidelines. Applicants respectfully request, therefore, that any subsequent Action issued in the present case provide the omitted information.

2.7 THE ALLEGED RESTRICTION IS INACCURATE

Applicants also note for the record, that there was no claim 56 pending at the time of the Requirement, and that claim 52 has not been identified to fall within any of the fifteen alleged restriction groups.

In order to reduce any further examination delays with respect to this issues, however, Applicants have taken these errors into account when formulating their enclosed amendment and provisional restriction election, and believe that the reply herein is complete and that prosecution on the merits can now begin.

2.8 REQUEST FOR RECONSIDERATION OF THE RESTRICTION

In view of the clear and convincing evidence from the International Examining Authority that the present application does not lack unity of invention, pursuant to 37 C. F. R. § 1.143, Applicants respectfully request reconsideration and modification of the restriction requirement. In particular, Applicants believe that at the very least, the imposition of Restriction Groups 4-12 for the subject matter of only 3 claims represents a *severe* economic burden on Applicants, and presents hardship upon Applicants with respect not only to prosecution, allowance, and future patent maintenance costs, but also greatly delays the issuance of patents directed to Applicants' invention.

Setting aside for the moment the contravention of the Unity of Invention finding in the parent case, and comparing the present application to other recent U.S. utility applications in the same art unit, Applicants believe that a more reasonable and less burdensome restriction requirement would, at the very worst, consider the subject matter of Claims 49 and 50 to be properly defined as a restriction group, and that the subject matter of Claims 51 and 52 be

defined as a separate restriction group, with claim 51 to be generic, and a *species* election for the species of diseases to be treated as listed in claim 52.

To that end, Applicants hereby formally request that the Office reconsider the alleged multi-way restriction which is clearly at odds with the previous Unity of Invention finding of the PCT and ask that the present Action be vacated and that either (a) no restriction be imposed and all pending claims considered together, or (b) the Office greatly reduces the number of alleged groups in order that examination of Applicants inventions are not unduly burdened by this Action.

2.9 APPLICANTS' PROPOSED RESTRICTION/ELECTION

In view of current Office practice, and mindful of the restriction/species election guidelines presently adopted by TC1600, Applicants respectfully request that if the present 15-way Restriction Requirement cannot be vacated in its entirety, and that all claims be examined together, at the very least they request that the Action be vacated, and a more reasonable restriction/species election form the basis for initial consideration on the merits of the claimed inventions.

In order to facilitate expedited examination of the present case, Applicants hereby propose the following restriction/species election to facilitate such examination:

Group 1 – Claims 1-15 drawn to methods of nuclear transfer.

Group 2 – Claims 16-46 drawn to methods of producing cloned animal embryos and embryonic cell lines.

Group 3 – Claims 49-50 drawn to methods of therapeutic cloning.

Group 4 – Claims 51-52 drawn to methods of treating a disease, disorder or injury by transplantation of specialized cells or tissue.

(If Group 4 invention is elected, as claim 51 is generic, Applicants would be requested to provisionally elect a single species from among the following species for initial examination: neurological disorder, diabetes, heart disease, muscular dystrophy, hereditary disease, cancer, spinal cord injury, burns, or other afflictions.)

Group 5 – Claim 53 drawn to a method of drug discovery or toxicology testing of drugs *in vitro*.

Group 6 – Claim 54 drawn to a method of xenotransplantation.

Group 7 – Claim 55 drawn to methods of gene therapy.

Applicants formally request that the present Action be vacated, and that at worst, it be reissued in a more reasonable restriction/election, as suggested herein. Such consideration on the part of the Office would be appreciated, as it would reduce not only the economic burden of simultaneously prosecuting large numbers of applications, and give consideration to the issues of patent term, but would also reduce the examination burden on the Offic.

In summary, Applicants respectfully request that the previous restriction be vacated, and that the proposed 7-way restriction/species election presented herein be adopted for subsequent prosecution on the merits.

2.10 PROVISIONAL ELECTION

Although disagreeing with the Office as to the issuance of a restriction requirement in the first place, especially in view of the unity of invention finding in the PCT phase of international prosecution of the related application, and particularly disagreeing with the Office as to the characterization of the subject matter of claims 49-51 as allegedly properly restrictable into 9

separate inventions, Applicants are nevertheless required to provisionally elect a group for initial examination. Pursuant to 37 C. F. R. § 1.111, and to that end, Applicants provisionally elect the Group I invention (claims 1-15) for examination. Newly added claims 56-66 are properly directed to the subject matter of the Group I restriction, and as such, are allowable for entry.

Applicants also note for the record, that should the Office accept Applicants' proposed 7-way restriction/species election, Applicants would elect the proposed Group I invention for initial examination without traverse.

2.11 SUPPORT FOR THE CLAIMS

Support for the pending claims can be found throughout the original claims, specification and figures as filed. It will be understood that no new matter is included within any of the newly-submitted claims. Applicants authorize any additional fees necessitated by the presently added claims to be deducted from Applicants' Representatives' Deposit Account as noted above.

2.12 REQUEST FOR EXAMINER INTERVIEW TO DISCUSS VACATION OF RESTRICTION

In order to facilitate an expedited examination of the present case, Applicants hereby indicate their willingness to work with the Examiner to achieve a fair and equitable balance between the burden upon Applicants for multiple restriction groups, and the burden upon the office for thorough examination of all invention.

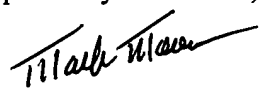
To that end, Applicants' undersigned representative affirms his willingness to discuss this issue with the Examiner and Supervisory Examiner Shukla once the Office has received and considered the present communication.

Applicants therefore request that the Examiner contact the undersigned representative within 30 days' receipt and consideration of the present response, and before issuance of a subsequent Action in the matter.

3.0 CONCLUSION

Applicants believe this to be a full, complete, and timely response to the outstanding restriction requirement. Should the Examiner have any questions, a telephone call to the undersigned Applicants' representative would be appreciated.

Respectfully submitted,



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